DEPARTMENT OF HEALTH AND HUMAN SERVICE

5Y2014

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

August 11, 2003

WARNING LETTER NO. 2003-NOL-23

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Oran F. Leger, Owner
Chez Francois Seafood
139 Tissington Street
Lafayette, Louisiana 70501

Dear Mr. Leger:

On June 18, 19, 24, and 26, 2003, our investigator inspected your seafood processing facility, located at 139 Tissington Street, Lafayette, Louisiana. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your crawfish tail meat and crab meat are **adulterated,** in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's Internet home page at http://www.fda.gov.

The deviations were as follows:

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can, as a result, be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for vacuum-packaged, cooked crawfish tail meat does not list the critical control point of labeling to control the food safety hazard of *Clostridium botulinum* (*C. botulinum*) toxin formation.

  We particularly are concerned with your failure to identify and to implement controls for *C. botulinum* toxin formation in your HACCP plan for crawfish. To prevent toxin production by *C. botulinum,* vacuum-packaged crawfish tail meat must be maintained in a frozen condition until immediately before use by the consumer. Also, it should be labeled with adequate storage instructions (such as "Important, keep frozen until used, thaw under refrigeration immediately before use").

Please note, in place of identifying "Labeling" as a critical control point, you have another option for frozen, vacuum-packaged product under HACCP. The product description on your HACCP plan may identify the product as "vacuum packed frozen crawfish tail meat, labeled 'Important, keep frozen until used, thaw under refrigeration immediately before use.'"

- You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice; condition and cleanliness of food contact surfaces; prevention of cross-contamination; maintenance of hand washing, hand sanitizing, and toilet facilities; protection of food, food packaging material, and food contact surfaces from adulteration with contaminants; proper labeling, storage, and use of toxic compounds; control of employee health conditions that could result in microbiological contamination; and, exclusion of pests from the food plant required for the processing of ready-to-eat, picked crabmeat.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

We are aware that you made a verbal commitment to correct the deviations during the inspection, and we have received your letter dated July 28, 2003. Your letter describes some of the corrections you have made in response to observations made during our inspection. However, they do not sufficiently address the deficiencies noted in the Form FDA 483 issued on June 26, 2003, at the close of our inspection. Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as copies of modified HACCP plan, sanitation control records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at 504-253-4519.

Sincerely,

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483